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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,888

11/12/2003

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NCPT-001

2298

23410 7590 09/12/2008
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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

09/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/712,888	Applicant(s) DADOURIAN, DANIEL G.	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 23-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 23-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to Applicant's after final amendment filed 14 August 2008.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

The rejection is replaced with the new final rejection below.

Response to Arguments

Applicant argues that Shakhovich does not disclose a locator that is provided in a retracted position and then expanded or a locator that partially encircles an interventional device. However, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that Shakhovich and Stewart are not properly combined because element 192 of Stewart is intended for use in ablating tissue outside the ostium. This is true, however, element 192 of Stewart is also disclosed as being used for locating the ostium and properly positioning/centering tip portion 208 within the vessel immediately inside the ostium (column 13, lines 32-61). Further, regarding Applicant's arguments that it is impossible to incorporate the teachings of Stewart into Shakhovich without substantial modification, the test for obviousness is not whether the

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features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Regarding Applicant's arguments that the locator of Stewart does not flatten out axially when the sheath is placed in contact with an ostium. This is not persuasive because the locator is disclosed as flexible (column 12, lines 50-57).

Regarding Applicant's arguments that Ischinger does not disclose an ostial locator that partially encircles an interventional device, this is not persuasive because the ostial locator overlaps the interventional device and this can be interpreted as "partially encircling".

Applicant's arguments that the ostial locator of Ischinger is cannot axially flattened when in contact with an ostium is persuasive and the rejection to Claim 29 under 35 U.S.C 102(b) under Ischinger is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ischinger (US Patent 6,682,556).

Claim 1: Ischinger'556 discloses a device with a sheath (14) adapted to be affixed to an interventional device (40 and balloon; see Figure 2a) and an ostial locator wire (15, 100) having a distal region capable of moving between an extended and retracted configuration (column 4, lines 23-34). The sheath is affixed to the interventional device (see Figure 2a).

Claim 23, 24: Ischinger'556 discloses a device that contains an interventional device (40 and balloon; see Figure 2a), a sheath (14) and an ostial locator (15, 100) disposed within the sheath that is capable of moving between an extended and retracted configuration (column 4, lines 23-34). Further, Ischinger'556 discloses that when deploying a stent at an ostium, multiple wires (15, 100) can be used to create an ostial locator that surrounds the stent (column 4, lines 29-32).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1, 7-14, 23-31, 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich et al. (US Patent 5,749,890) in view of Stewart et al. (US Patent 6,572,612).

Claim 1: Shaknovich'890 teaches a sheath (16) and an ostial locator device (3) disposed within the sheath having a distal region that is in a retracted configuration within the sheath (3c; Figure 9) and an expanded configuration (3d; Figure 12-14) outside the sheath and retracted again when placed back into the sheath (Figure 15).

Shaknovich'890 does not teach that the ostial locator is a wire.

Stewart'612 teaches an ostial locator (Figure 8) that is comprised of a wire (192) that extends from a sheath to an expanded configuration (column 13, lines 31-61). It would have been obvious to one of ordinary skill in the art to substitute a known equivalent element (ostial locator balloon taught by Shaknovich) for another (ostial locator wire taught by Stewart) to obtain predictable results.

Claim 7: Shaknovich'890 teaches that the expanded configuration is sized to be larger than the ostium (Figure 13) Also, Stewart'612 teaches that the expanded configuration is larger than the diameter of the ostium (see Figure 3a)

Claim 8, 9, 10: Stewart'612 teaches that the expanded configuration is a spiral shape (see Figure 8).

Claim 11: The last coil of Stewart'612 is capable of serving as a lasso.

Claim 12: Shaknovich'890 teaches a stent (6).

Claim 13, 14: The expanded configuration of the ostial locator wire of Stewart is capable of flattening out when in contact with the ostium (column 6, lines 25-28).

Claim 23: Shaknovich'890 teaches an interventional device (6), a sheath (16) and an ostial locator device (3) disposed within the sheath having a distal region that is in a retracted configuration within the sheath (3c; Figure 9) and an expanded configuration (3d; Figure 12-14) outside the sheath and retracted again when placed back into the sheath (Figure 15).

Shaknovich'890 does not teach that the ostial locator surrounds the stent.

Stewart'612 teaches an ostial locator (Figure 8) that is comprised of a wire (192) that extends from a sheath to an expanded configuration and surrounds a device (196) that is being placed within an ostium. It would have been obvious to one of ordinary skill in the art to substitute a known equivalent element (ostial locator balloon taught by Shaknovich) for another (ostial locator wire taught by Stewart) to obtain predictable results.

Claim 24: The interventional device of Shaknovich'890 teaches that the stent (6) surrounds a balloon (11).

Claim 25: The ostial locator of Shaknovich'890 has a distal region that is in a retracted configuration within the sheath (3c; Figure 9) and an expanded configuration (3d; Figure 12-14) outside the sheath and retracted again when placed back into the sheath (Figure 15). The ostial locator of Shaknovich'890 is not a wire.

Stewart'612 teaches an ostial locator (Figure 8) that is comprised of a wire (192) that extends from a sheath to an expanded configuration. It would have been obvious to one of ordinary skill in the art to substitute a known equivalent element (ostial locator balloon taught by Shaknovich) for another (ostial locator wire taught by Stewart) to obtain predictable results.

Claim 26: The expanded configuration of the ostial locator wire of Stewart is capable of flattening out when in contact with the ostium (column 6, lines 25-28).

Claim 27, 28: Shaknovich'890 teaches the use of a delivery catheter (4).

Claim 29-31, 33-34: Shaknovich'890 teaches an interventional device (6), a sheath (16) and an ostial locator device (3) disposed within the sheath having a distal region that is in a retracted configuration within the sheath (3c; Figure 9) and an expanded configuration (3d; Figure 12-14) outside the sheath and retracted again when placed back into the sheath (Figure 15).

Shaknovich'890 does not teach that the ostial locator surrounds the stent.

Stewart'612 teaches an ostial locator (Figure 8) that is comprised of a wire (192) that extends from a sheath to an expanded configuration and surrounds a device (196) that is being placed within an ostium. The expanded configuration of the ostial locator wire of Stewart is three-dimensional coil and capable of flattening out when in contact with the ostium (Figure 8 and column 6, lines 25-28). It would have been obvious to one of ordinary skill in the art to substitute a known equivalent element (ostial locator balloon taught by Shaknovich) for another (ostial locator wire taught by Stewart) to obtain predictable results.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich'890 in view of Stewart'612 as applied to claim 1 above, and further in view of Hoyns et al. (US 6,766,186).

Shaknovich'890 teaches the use of radiopaque markers. It is old and well known to use radiopaque markers on devices placed inside the body so that the surgeon can view the location of the device.

Further, Stewart'612 teaches that the ostial locator wire can be made of nitinol.

Hoyns'186 teaches that nitinol is radiopaque, ultrasonically opaque, and MRI compatible (see col. 4, lines 31-36).

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich'890 in view of Stewart'612 as applied to claim 1 above, and further in view of Ravenscroft (US Patent 5,702,418).

Shaknovich'890 in view of Stewart'612 teach the limitations of Claim 32 except for a stop that limits the distal end from being over extended.

Stops that prevent overextension of devices into the body are old and well known in the art, as for example, the stop (26) taught by Ravenscroft stops the distal end of the element 15 from overextending into the body. It would have been obvious to one of ordinary skill in the art to modify the device taught by Shaknovich'890 in view of Stewart'612 with a stop in order to prevent the distal end from over extending into the body and possibly getting lost or left behind causing harm to the patient.

Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaknovich'890 in view of Stewart'612, as applied to Claim 1, in further view of McGuckin, et al. (US Patent 6,589,214).

Shaknovich'890 in view of Stewart'612 teaches that the sheath is attached to the interventional device, but does not disclose what is used to attach the interventional device and sheath. Shaknovich'890 in view of Stewart'612 does not teach a specific method of attaching the sheath to the interventional device, however, it is old and well known in the art to attach using clasps and sheaths. Further, the multiple attachment methods claimed are obvious variants of one another.

McGuckin'214 teaches an introducer sheath containing a fastener (40) that can be used to attach an interventional device to a sheath (21). Regarding Claim 3, the fastener (40) comprises a thin flexible sheet that can wrap around an interventional device. Regarding Claim 4 and 5, the fastener contains a clasp (85) (column 6, lines 21-28), which is friction fit into engagement with the fastener (40) so the fastener can retain an interventional device (column 6, lines 21-28). Regarding Claim 6, the clasp (85) is adapted to be fit to an interventional device using a biocompatible adhesive. It would have been obvious to one skilled in the art at the time the invention was made to modify Shaknovich'890 in view of Stewart'612 with a different attachment mechanism, such as the one taught by McGuckin'214 to make sure that the sheath and an interventional device are securely fastened to each other and not lost in the patient's body.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./

Examiner, Art Unit 3734

/Darwin P. Erezol

Primary Examiner, Art Unit 3773